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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,522	06/28/2001	Maria A. Glucksmann	381552001700	7750

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INTELLECTUAL PROPERTY GROUP
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EXAMINER
SWOPE, SHERIDAN

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 09/16/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/896,522	GLUCKSMANN, MARIA A.	
	Examiner	Art Unit	
	Sheridan L. Swope	1652	

-- The MAILING DATE of this c mmunication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, and 6, and 8, in part, drawn to nucleic acid molecules, classified in class 435, subclass 6.

II. Claim 4, drawn to polypeptides, classified in class 435, subclass 194.

III. Claims 8, in part, and 5, drawn to antibodies, classified in class 530, subclass 388.26.

IV. Claims 7 and 22, in part, and 11 and 14, drawn to methods of identifying a nucleic acid using Northern blotting, classified in class 435, subclass 6.

V. Claims 7 and 22, in part, 13 and 16, drawn to methods for detecting a polypeptide using a binding reaction, classified in class 435, subclass 7.1.

VI. Claim 9, in part, drawn to a method for identifying a compound which binds to a polypeptide, classified in class 435, subclass 15.

VII. Claims 9 and 17, in part, drawn to a method for identifying a compound which modulates the activity of a polypeptide, classified in class 435, subclass 15.

VIII. Claims 10 and 15, drawn to a method for modulating the activity of a polypeptide, classified in class 435, subclass 194.

IX. Claim 12, drawn to methods of identifying a nucleic acid using amplification, classified in class 435, subclass 252.3.

X. Claim 17, in part, drawn to a method of assaying the ability of a compound to modulate nucleic acid expression, classified in class 435, subclass 6.

XI. Claims 18-20, in part, drawn to a method of treatment comprising administering a modulator of a nucleic acid molecule, classified in class 514, subclass 789.

XII. Claims 18-20, in part, drawn to a method of treatment comprising administering a modulator of a polypeptide, classified in class 514, subclass 789.

XIII. Claim 21, in part, drawn to a method for evaluating efficacy of a treatment using Northern blotting, classified in class 435, subclass 6.

XIV. Claim 21, in part, drawn to a method for evaluating efficacy of a treatment using a binding reaction for a polypeptide, classified in class 435, subclass 7.1.

XV. Claim 22, in part, drawn to a method for assaying the activity of a nucleic acid molecule, classified in class 435, subclass 6.

XVI. Claim 22, in part, drawn to a method for assaying the activity of a polypeptide, classified in class 435, subclass 15.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Also, product and process inventions are distinct if any of the following can be shown: (1) that the process as claimed can be used to make another and materially different product, (2) that the product claimed can be used in a materially different process of using that product, or (3) that the product claimed can be made by another and materially different process (MPEP § 806.05(h)). These inventions are different or distinct for the following reasons.

The nucleic acids of Invention I are related to the protein of Invention II by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the protein

in host cells. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The DNA of Invention I and the antibodies of Invention III are unrelated because they are physically and functionally distinct chemical entities.

The proteins of Invention II are related to the antibodies of Invention III by virtue of being the cognate antigen necessary for the production of antibodies. Although the protein and antibody are related due to the necessary steric complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities and because the protein can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right.

The DNA of Inventions I is unrelated to the methods of Inventions V-VIII, XI, XII, and XIV-XVI because said methods cannot use the DNA of Invention I nor be used to make said DNA.

The polypeptides of Invention II are unrelated to the methods of Inventions IV, VIII-XIII, and XV because said methods cannot use the polypeptides of Invention II nor be used to make said polypeptides.

The antibodies of Invention III are unrelated to the methods of Inventions IV, IX, X, XI, XIII, and XV because said methods cannot use the antibodies of Invention III nor be used to make said antibodies.

The methods of Inventions IV, IX, X, and XIII are related to the DNA of Invention I as a product and process of using. However, the inventions are distinct because the DNA can also be used for recombinant production of the encoded protein.

The methods of Inventions V-VII, XIV, XVI are related to the polypeptides of Invention II as a product and process of using. However, the inventions are distinct because the polypeptides can also be used for making antibodies.

The methods of Inventions V-VIII, XII, XIV and XVI are related to the antibodies of Invention III as a product and process of using. However, the inventions are distinct because the antibodies can also be used for purification of the target protein.

The methods of Inventions IV-XVI are distinct because they comprise different steps, utilize different products and/or produce different results.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art due to their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention.

For Inventions XI and XII:

A. A small molecule;

B. Peptide;

C. Phosphopeptide;

D. Anti-57658 antibody;

E. A 57658 polypeptide comprising SEQ ID NO: 2, or a fragment thereof;

F. A 57658 polypeptide having at least 90% identity with SEQ ID NO: 2;

G. An allelic variant of a polypeptide of SEQ ID NO: 2;

H. An antisense 57658 nucleic acid molecule;

I. A ribozyme;

J. The polynucleotide of SEQ ID NO: 1, or a fragment therof;

K. A nucleic acid molecule encoding a polypeptide having at least 90% identity with SEQ ID NO: 2;

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 18 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 703-305-1696. The examiner can normally be reached on M-F; 8:30-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

REBECCA E. PRUTY
PRIMARY EXAMINER
GROUP ~~1300~~
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